Atty. Docket No.:

1133/2002

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of:

Jones, et al.

Serial No.:

10/083,246

Filed:

February 26, 2002

Entitled:

COMPOSITIONS AND METHODS

FOR GENETIC ANALYSIS OF

POLYCYSTIC KIDNEY DISEASE

Examiner:

Not Yet Assigned

Group Art Unit:

1645

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Conf. No.:

6437

JUN 2 4 2003

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Brenda M Woods

Name of Person Mailing Paper

Commissioner for Patents P.O. Box 1450 **Alexandria, VA 22313-1450**

TRANSMITTAL LETTER

Enclosed for filing in the above-identified patent application, please find the following documents:

- Information Disclosure Statement;
- 2. Form PTO-1449;
- 3. Copies of Cited References; and
- 4. Return Post Card.

The Commissioner for Patents is hereby authorized to charge any additional fees or credit any overpayment in the total fees to Deposit Account No. 16-0085, Reference No. 1133/2002. A duplicate of this transmittal letter is enclosed for this purpose.

Respectfully submitted,

Date:

June 20, 2003

11.6011 Name: Mark J. FitzGerald

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111 Huntington Avenue Boston, MA 02199-7613

Tel: 617-239-0100



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CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8a

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Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT **UNDER 37 CFR §§§ 1.56, 1.97 AND 1.98**

Dear Sir:

In accordance with the duty of disclosure under 37 CFR § 1.56, Applicant submits this Information Disclosure Statement pursuant to 37 CFR §§ 1.97 and 1.98 in the above-identified application for consideration by the Patent Office. A listing of the cited documents is also enclosed, as well as, for the Examiner's convenience, copies of the documents in the list.

Pursuant to CFR § 1.97(e)(1), items 2, 4-15 contained in the Information Disclosure Statement were first cited in a communication from a foreign patent office in a counterpart foreign application or International application. Because this statement is being filed within three months of receipt of the Search Report and before the first Office Action on merit, no fee is believed to be due. A copy of the Search Report is included and cited on the enclosed PTO-1449.

Applicant does not intend to represent that any of the documents submitted herein are material prior art to this invention or that the list represents an exhaustive search of documents related to this invention.

Applicant respectfully requests that the documents submitted herein be considered and made of record in this application.

Respectfully submitted,

Date: June 20, 2003

> Name: Mark J. FitzGerald Registration No.: 45,928 Palmer & Dodge LLP 111 Huntington Avenue Boston, MA 02199-7613

Tel: 617-239-0100

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Page 1 of 2

Serial No. epartment of Commerce Attorney Docket No. Patent and Trademark Office 10/083,246 1133/2002 INFORMATION DISCLOSURE STATEMENT Applicant(s):. Jones, et al. Filing Date: February 26, 2002 Group: 1645 U.S. PATENT DOCUMENTS Filing Date Name Class Subclass Examiner Patent No. Date (if appropriate) Initial Jan. 9, 2003 435 6 Jul. 13, 2001 2003/0008288 A1 Germino, et al. 1. Jun. 4, 1996 6,071,717 Jun. 6, 2000 Klinger, et al. 69.1 2. 435 FOREIGN PATENT DOCUMENTS Country Subclass Translation Document No. Publication Class Examiner Date Initial YES NO WO 02/06529 A2 **PCT** C12Q 3. 1/68 X Jan. 24, 2002 OTHER DOCUMENTS (including Author, Title, Date, Pertinent Pages, etc.) Phakdeekitcharoen, B. et al., (2001), "Mutation Analysis of the Entire Replicated Portion of PKD1 4. Using Genomic DNA Samples", J. Am. Soc. Nephrol, 12:955-963. 5. Perrichot, R.A. et al., (1999), "DGGE screening of PKD1 gene reveals novel mutations in a large cohort of 146 unrelated patients", Hum. Genet., 105:231-239. Thomas, R. et al., (1999), "Identification of Mutations in the Repeated Part of the Autosomal Dominant 6. Polycystic Kidney Disease Type 1 Gene, PKD1, by Long-Range PCR", Am. J. Hum. Genet., 65:39-49. Watnick, T. et al., (1999), "Mutation Detection of PKD1 Identifies a Novel Mutation Common to 7. Three Families with Aneurysms and/or Very-Early-Onset Disease", Am. J. Hum. Genet., 65:1561-1571. Watnick, T.J. et al., (1998), "Somatic Mutation in Individual Liver Cysts Supports a Two-Hit Model of 8. Cystogenesis in Autosomal Dominant Polycystic Kidney Disease", Molecular Cell, 2:247-251. 9. Roelfsema, J.H. et al., (1997), "Mutation Detection in the Repeated Part of the PKD1 Gene", Am. J. Hum. Genet., 61:1044-1052. Watnick, T.J. et al., (1997), "An unusual pattern of mutation in the duplicated portion of *PKD1* is 10. revealed by use of a novel strategy for mutation detection", Human Molecular Genetics, 6(9):1473-1481. Neophytou, P. et al., (1996), "Detection of a novel nonsense mutation and an intragenic polymorphism 11. in the PKD1 gene of a Cypriot family with autosomal dominant polycystic kidney disease", Hum. Genet., 98:437-442. Peral, B. et al., (1996), "Screening the 3' Region of the Polycystic Kidney Disease 1 (PKD1) Gene 12. Reveals Six Novel Mutations", Am. J. Hum. Genet., 58:86-96. Turco, A.E. et al., (1995), "A novel nonsense mutation in the PKD1 gene (C3817T) is associated with 13. autosomal dominant polycystic kidney disease (ADPKD) in a large three-generation Italian family", Human Molecular Genetics, 4(8):1331-1335. Ward, C.J. et al., (1995), "Homo sapiens polycystic kidney disease-associated protein (PKD1) gene, 14. complete cds", Database EMBL Online, Database Accession No. L39891:1-20.



15. International Search Report of International Application No. PCT/US01/22035.

EXAMINER

DATE CONSIDERED

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

^{**}Copies of references not provided at the time of this submission.